

August 25, 1995

K954053

Summary of Safety and Effectiveness

MAY 16 1996

Encore Orthopedics®, Inc.  
8920 Business Park Drive  
Suite 380  
Austin, TX 78759  
512-795-8696  
J.D. Webb

Trade Name: Berlin External Fixator

Common Name: External Fixator

Classification Name:

Description and Indications: The Berlin External Fixator is a wire connected ring or frame fixator. It can be used as a static fixator or dynamically applying distraction or compression. The Berlin Fixator has been designed as a modular construction system. Through the use of a few individual components, simple static fixation procedures can be achieved. The range of indications includes treatment of acute fractures and reconstructive surgery of all long bones. This device is made from a combination of aluminum and stainless steel.

Comparable Features to Predicate Device(s): This device is similar in indications and characteristics to the Ilizarov device marketed by Smith-Nephew Richards.

Test Results: Three different assemblies of the Berlin Fixator, along with the Ilizarov fixator, were tested in static and dynamic compression. The Berlin Fixator test assemblies consisted of the small, medium and large diameter rings. This testing showed that the static load to failure for the Berlin and Ilizarov fixators was the same, i.e. 600 N. At a maximum cyclic load of 300 N the three Berlin Fixator assemblies survived 226,000, 194,000 and 253,000 cycles. This compared to the Ilizarov at 346,000 cycles.